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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,628	04/27/2001	Joseph Roberts	023032/0108	9388

22428 7590 04/20/2004

FOLEY AND LARDNER  
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EXAMINER

BROWN, TIMOTHY M

ART UNIT PAPER NUMBER

1648

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/842,628

Applicant(s)

ROBERTS ET AL.

Examiner

Tim Brown

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24-30 and 47-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 24-30 and 47-57 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2. According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-V do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of Group I is a cell-free glutaminase preparation which is shown by Davidson et al.<sup>1</sup> to lack novelty or inventive step and does not make a contribution over the prior art.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

**Group I, claims 24-27, 29, 30 and 48-50 drawn to a cell-free preparation of *Pseudomonas* glutaminase.**

**Group II, claims 24 and 28, drawn to a product by process using DNA in a recombinant microorganism to obtain therapeutically suitable glutaminase.**

**Group III, claim 47 drawn to a nucleic acid comprising SEQ ID NO: 1.**

**Group IV, claims 51-57, drawn to a method for producing glutaminase through the cell culture of a recombinant microorganism.**

Groups I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

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functions, or different effects (MPEP § 806.04, MPEP § 808.01). Group I is unrelated to Group II in that Group I drawn to *Pseudomonas* glutaminase while Group II is drawn to glutaminase derived from a recombinant microorganism. Being derived from different genomes, the glutaminase from each of Groups I and II would have distinct amino acid sequences and distinct physical properties. Thus, Groups I and II have different effects. Group III is unrelated to Groups I and II for being directed to a nucleic acid sequence. Unlike the glutaminase proteins of Groups I and II which function as enzymes, the nucleic acid sequence of Group III serves to encode a protein. Accordingly Group III has a different mode of operation than Groups I and II. For at least these reasons, Groups I-III are unrelated.

Groups I and II are related to Group IV as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, Groups IV is drawn to a method of producing glutaminase using bacterial cell culture. The glutaminase of Group I and the glutaminase of Group II can each be made by a materially different process because each glutaminase can be purified from cell homogenates using affinity chromatography. Accordingly, Groups I and II are distinct from Group IV.

Group III and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

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<sup>1</sup> Davidson L. "Purification and Properties of an L-Glutaminase-L-Asparaginase from *Pseudomonas acidovorans*" *Journal of Bacteriology* (March 1997) pp. 1379-1386

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§ 806.05(h)). In the instant case, the nucleic acid of Group III is can be used in a materially different process in that in can be used as a genetic probe to detect the presence of a glutaminase gene. Accordingly, Groups III and IV are distinct.

Claim 24 links the inventions of Group I and Group II. The restriction requirement between the linked inventions is subject to the nonallowance of linking claim 24. Upon the allowance of this linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tim Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tim Brown  
Examiner  
Art Unit 1648

tmb

  
**ULRIKE WINKLER, PHD.**  
**PATENT EXAMINER** 4/16/04